Complete Summary

GUIDELINE TITLE

Benign prostatic hyperplasia.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Benign prostatic hyperplasia. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Sep 18 [Various].

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- November 22, 2005, Flomax (tamsulosin HCl): Revisions were made to PRECAUTIONS and ADVERSE REACTIONS sections of the prescribing information for Flomax due to the observation of Intraoperative Floppy Iris Syndrome (IFIS) in some patients treated with alpha-1 blockers, including Flomax.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Benign prostatic hyperplasia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Urology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Men with suspected or confirmed benign prostatic hyperplasia

INTERVENTIONS AND PRACTICES CONSIDERED

Primary Investigations

1. Assessment of signs and symptoms
2. Symptom questionnaire (e.g., International Prostatic Symptom Score [IPSS])
3. Writing down details associated with voiding
4. Digital rectal examination (DRE)
5. Urinalysis
6. Serum/plasma creatinine
7. Serum prostate-specific antigen (PSA)
8. Residual urine volume as determined by ultrasonography or catheterization

Investigations Performed by Urologist

1. Urine flow measurement
2. Transrectal ultrasonography

3. Cystometry and pressure-flow examination
4. Urethrocystography
5. Urography
6. Prostatic biopsies
7. Cystoscopy

Treatment

1. Conservative treatment
2. Drug treatment
    - Alpha$_1$-blockers
    - 5-alpha-reductase inhibitors
    - Combination of 5-alpha-reductase inhibitor and alpha$_1$-blocker
3. Surgical and other invasive treatments
    - Transurethral resection of the prostate (TURP)
    - Transurethral incision of the prostate (TUIP)
    - Open prostatectomy
    - Thermotherapy (microwave treatment)
    - Stent or spiral
4. Catheter
    - Percutaneous cystostomy or catheterization
    - Repeated catheterization
    - A silicon catheter with the balloon filled with hypertonic (5%) saline or glyserol

Follow-up Treatment after Transurethral Resection of the Prostate

1. Urine bacterial culture
2. Antibiotics (if bacterial infection is detected)
3. Pelvic floor muscle exercises for stress incontinence
4. Antimuscarinic drugs for urge incontinence and nocturia

Note: Pygeum africanum and phytotherapy with Hypoxis rooperi, Secale cereale, Urtica dioica, or Curcubita pepo were considered but not specifically recommended.

MAJOR OUTCOMES CONSIDERED

- Effect of treatment on factors such as symptoms, prostate volume, peak urinary flow, residual urine volume, urinary flow rate, risk of overall clinical progression
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the database of abstracts of reviews of effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

Aims

- The diagnosis of benign prostatic hyperplasia is based on symptoms and basic investigations. Other causes of voiding disturbances (prostate cancer in particular) are excluded.
- Conditions requiring surgical management are recognized.
- Follow-up alone or drug therapy are good options in patients with relatively mild symptoms and no complications of urinary tract stricture.

Symptoms

- Storage symptoms
    - Extraordinary voiding frequency
    - Nocturia
    - Urinary urgency
    - Urge incontinence
- Voiding symptoms
    - Difficulty in the initiation of voiding
    - Poor urine flow
    - Need to strain while voiding
    - Discontinued voiding
    - Feeling of inadequate bladder emptying
    - Urinary retention

Primary Investigations

- Symptom questionnaire
    - A commonly used questionnaire is International Prostatic Symptom Score (IPSS)
    - The questionnaire is useful in the assessment of severity of symptoms when decisions are made between follow-up, drug treatment, and surgery.
- Writing down details associated with voiding
- DRE (digital rectum examination)

- Urinalysis
- Serum/plasma creatinine
- Serum prostate-specific antigen (PSA)
- Residual urine volume is determined by ultrasonography (see the Finnish Medical Society Duodecim guideline "Determining the Volume of Residual Urine by Ultrasonography") (or, if ultrasonography is not available, by catheterization). Ultrasonography is useful in the determination of prostatic size (calculated with the same equation as residual urine volume [see the Finnish Medical Society Duodecim guideline "Determining the Volume of Residual Urine by Ultrasonography"]), shape, and eventual hydronephrosis.
- Differential diagnosis, see table below.

Table: Differential Diagnosis on Benign Prostatic Hyperplasia

Condition or Disease	History or Finding
Prostate cancer	Finding in DRE, elevated serum PSA concentration
Urinary bladder cancer	Haematuria, abnormal cytological finding
Bladder calculi	Haematuria, ultrasonography finding
Urethral stricture	Box-shaped flow curve
Stricture of the bladder neck	Earlier invasive treatment
Bladder neck dyssynergia	Small prostate gland, disturbing symptoms associated with voiding
Prostatitis	Tender prostate gland
Overactive bladder	Urgency with possible urge incontinence

Indications for Specialist Consultation

Indications for Diagnostic Investigations by the Urologist

- The patient is below 50 years of age.
- DRE is suspicious (nodules).
- Serum PSA is above 10 micrograms/L (above 3 micrograms/L in patients below 65 years of age).
    - If the serum total PSA concentration is in the range of 3 to 10 micrograms/L, measuring free/total PSA ratio is recommended. If this value is under 0.15, the probability of prostatic cancer is increased (Walsh, 1996) and a urologist should be consulted.
    - DRE before determination of serum PSA level does not influence the result.
- Rapidly developing symptoms
- Haematuria (cystoscopy)
- Diabetics who may have neuropathy
- History of pelvic surgery or irradiation
- Neurological disease or injury affecting the function of the urinary bladder
- Necessary medication affecting the function of the urinary bladder
- Lower abdominal pain as the main symptom
- Discrepancy between symptoms and findings
- The investigations performed by the urologist usually include:
    - Urine flow measurement
    - Transrectal ultrasonography

- And if necessary also
    - Cystometry and pressure-flow examination (recommended before deciding on surgery if the peak flow is >10 mL/s and also when there is a discrepancy between symptoms and findings or the patient has undergone surgery of the lower urinary tract)
    - Urethrocystography
    - Urography
    - Prostatic biopsies
    - Cystoscopy

Surgical Treatment Is Indicated in the Following Cases

- Urinary retention, overflow incontinence, or repeatedly more than 300 mL of residual urine
- Severe symptoms not relieved by drug therapy
- Severe narrowing based on measurement of flow rate
- Dilatation of the upper urinary tract
- Impairment of renal function
- Recurrent macroscopic haematuria
- Urinary tract infections
- Bladder calculi
- Severe or moderate symptoms in a patient who wants rapid relief or if satisfactory results have not been obtained with other treatments

Conservative Treatment

Follow-up

- As the symptoms of benign prostatic hyperplasia (BPH) vary greatly and the course of the disease in an individual cannot be fully predicted, follow-up is a suitable approach in patients with mild symptoms. Also in moderate symptoms, follow-up can be the initial approach if the symptoms do not essentially affect the quality of life and complications have not developed.
- Follow-up includes explaining to the patient the nature of the disease and carrying out basic investigations annually or when symptoms have changed. Opportunistic follow-up during other encounters in primary care is one method of screening.

Drug Treatment

- Although the effectiveness of drug treatment is not as good as that of surgery it is often sufficient for reducing or alleviating the symptoms.
- When deciding on the treatment, cost-effectiveness should also be evaluated (i.e., when would invasive therapy, which usually gives complete cure, cost less and be more convenient for the patient than drug therapy continuing for years [for example, to avoid one invasive treatment, 20 men have to be treated with finasteride for 4 years]). Transurethral resection is more cost-effective than drug treatment.
- Patients on drug treatment should be followed up regularly at 6- to 12-month intervals to detect complications resulting from urethral obstruction.
- The size of the prostate and total serum PSA determine the selection of the therapy (Boyle, Gould, & Roehrborn, 1996; Boyle et al., 2003) [C]. If the

prostate is not markedly enlarged on palpation or in ultrasonography (<40 g) and PSA is <1.5 micrograms/L, the first choice is an alpha$_1$-blocker (e.g., tamsulosin or alfuzosin) (Lepor et al., 1996; Boyle, Gould, & Roehrborn, 1996). If the prostate is markedly enlarged or PSA is >1.5 micrograms/L, either 5-alpha-reductase inhibitor (finasteride, dutasteride) (Wilde & Goa, 1999; Roehrborn et al., 2002; Debruyne et al., 2004) [A] or an alpha$_1$-blocker can be used.

- A combination of 5-alpha-reductase inhibitor and alpha$_1$-blocker alleviates symptoms more effectively than either drug alone (McConnell et al, 2003) [B].

Alpha-blockers

- Tamsulosin (Wilt, MacDonald, & Rutks, 2002) [A], alfuzosin, doxazosin, terazosin, and prazosin
- Alpha$_1$-blockers (Webber, 2005) [A] decrease symptoms, increase peak urinary flow, and reduce the volume of residual urine significantly more than placebo.
- The effect of alpha$_1$-blockers is seen rapidly, and it has been shown to continue for several years.
- The patients should be followed up initially at 1- to 3-month intervals.
- The side effects include dizziness, postural hypotension, and retrograde ejaculation. With selective tamsulosin and alfuzosin the risk of hypotension is lower.

5-alpha-reductase inhibitors (5ARI)

- The dose of finasteride is 5 mg x 1 and that of dutasteride is 0.5 mg x 1.
- The symptoms are alleviated, the urine flow is increased, and the obstruction is decreased (Wilde & Goa, 1999; Roehrborn et al., 2002; Debruyne et al., 2004) [A].
- The effect is at its best in patients with large prostates (Boyle, Gould, & Roehrborn, 1996; Boyle et al., 2003) [C] (Walsh, 1996).
- The effect starts slowly, sometimes as late as 6 months after the onset of treatment. If no effect is observed in 6 months the indications for surgery should be reconsidered.
- The drug decreases prostatic size but the prostate returns to its original size a few months after discontinuation of treatment.
- Impotence may occur as an adverse effect.
- Although treatment with 5-alpha-reductase inhibitors decreases serum PSA level by about 50% this makes follow-up no more difficult than with alpha-blockers: an increasing PSA concentration is an indication for investigation by a urologist.

<u>Surgical and Other Invasive Treatments</u>

- Transurethral resection of the prostate (TURP) (Webber, 2005) [A]
    - The only treatment for complicated prostatic hyperplasia and the best documented treatment for uncomplicated disease
    - Results very seldom in erectile dysfunction (though in most cases already before operation), almost always retrograde ejaculation.
- Transurethral incision of the prostate (TUIP)

    - Suitable for patients with prostates <30 mL in volume and with no prominent median lobe protruding towards the bladder
- Open prostatectomy
    - Rarely used nowadays (prostate >100 mL)
- Thermotherapy (microwave treatment) (Webber, 2005) [A]
    - Alleviates irritative symptoms
    - Long-term results are not available
- Stent or spiral
    - Can be used in selected cases in patients with a poor general condition

Catheter

- Percutaneous cystostomy is indicated in patients with urinary retention waiting for surgery.
- In selected cases repeated catheterization can be used (preferably by the patient himself).
- A silicon catheter with the balloon filled with hypertonic (5%) saline or glyserol can be used, but percutaneous cystostomy is preferred.

Treatment after Transurethral Resection of the Prostate (TURP)

- Urine bacterial culture should be taken routinely 4 to 6 weeks after the operation to detect bacteriuria, and always if a urinary tract infection is suspected (pyuria and haematuria may occur as long as 3 months after the operation).
- If bacterial growth is detected, antibiotics are indicated.
- Stress incontinence may be alleviated within 1 year: exercises of pelvic floor muscles may help.
- Antimuscarinic drugs (oxybutynin, tolterodine, trospium chloride, or solifenacin) can be used for the treatment of urge incontinence and nocturia.

Related Evidence

- Pygeum africanum may have some efficacy for benign prostatic hyperplasia (Wilt et al., 1998) [C].
- Phytotherapy with Hypoxis rooperi or Secale cereale may improve symptoms of benign prostatic hyperplasia. Urtica dioica or Curcubita pepo may not be effective when used alone. Phytotherapies are well tolerated (Wilt et al., 2000) [C].

Definitions:

Levels of Evidence

A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
C. Limited research-based evidence. At least one adequate scientific study.
D. No research-based evidence. Expert panel evaluation of other information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnostic evaluation and treatment of benign prostatic hyperplasia

Subgroups of Patients Within Target Population Most Likely to Benefit

Finasteride is most effective in men with large prostates.

POTENTIAL HARMS

- Side effects of alpha$_1$-blockers include dizziness, postural hypotension, and retrograde ejaculation.
- Finasteride may cause impotence.
- Transurethral resection of the prostate may cause urinary tract infection, stress incontinence, urge incontinence, nocturia, retrograde ejaculation, and very seldom, erectile dysfunction.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Benign prostatic hyperplasia. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2006 Sep 18 [Various].

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr 30 (revised 2006 Sep 18)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Teuvo Tammela

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

This guideline is included in "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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